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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/680,310	10/06/2000	Frank Elischwesi	PM268418	9029

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1100 New York Avenue, N.W.
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EXAMINER

LEFFERS JR, GERALD G

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 12/20/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/680,310

Applicant(s)

ELISCHWESKI ET AL.

Examiner

Gerald G Leffers Jr.

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/416,756.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of applicants' preliminary amendment, filed 10-6-01 as Paper No. 2, in which claims 21-28 were cancelled. Claims 1-20 are pending in the instant application.

Receipt is acknowledged of an information disclosure statement, filed 7-24-01 as Paper No. 4. The signed and initialed PTO-1449 has been mailed with this action.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c). The date for Jorn Kalinowski has been changed without being initialed.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because sequences were set forth that lack sequence identifiers, no computer readable format (CRF) was filed, no paper sequence was filed and no attorney statement was filed. These sequences include **the sequences throughout the specification (e.g. Figure 9, pages 17, 25 or 27)**. If the Sequence Listing required for the instant application is identical to that of another application, a letter may be submitted requesting transfer of the previously filed sequence information to the instant application. For a sample letter requesting transfer of sequence information, refer to MPEP § 2422.05. Additionally, it is often convenient to identify sequences in figures by amending the Brief Description of the Drawings section (see MPEP § 2422.02).

Applicants are required to comply with all of the requirements of 37 CFR 1.821 through 1.825. Any response to this office action that fails to meet all of these

requirements will be considered non-responsive. The nature of the noncompliance with the requirements of 37 C.F.R. 1.821 through 1.825 did not preclude the continued examination of the application on the merits, the results of which are communicated below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 18-20 are drawn towards plasmid vectors deposited in bacterial strains. Because it is not clear that the identical plasmids are freely available, or can be reproducibly constructed, a biological deposit for patenting purposes is required. It is noted that applicants indicate in the specification that the plasmid/host cell strains have been deposited under terms of the Budapest Treaty. However, there is no indication of the date of deposit or that all restrictions on the availability of the deposited material will be lifted. It would be remedial to amend the specification to include the date of deposit and to submit a statement by an attorney of record over his or her signature and registration number, stating that the specific material will be irrevocably and without restriction or condition released to the public upon the issuance of a patent.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 4-20 are all vague and indefinite in that the claims lack an article (e.g. A or The) at the beginning of the claim.

Claim 1 is vague and indefinite in that the metes and bounds of the phrase "... by amplification of nucleotide sequences which code for ketopantoate reductase individually or in combination with one another, and optionally additionally of the ilvC gene ..." are unclear. It is unclear, for example, which sequences or combination of sequences encoding ketopantoate reductase are referred to by the phrase. It is also unclear with what sequences the ilvC gene is to be amplified. It would be remedial to amend the claim language to more clearly indicate those sequences which can be amplified, or co-amplified, to produce pantothenic acid.

Claims 7 and 8 are vague and indefinite in that the use of the term "and/or" makes it unclear which combinations of limitations need be met in order to practice the claimed method. Claim 7 is also vague and indefinite in that it is unclear as the claim is written whether the term "one or more" modifies "antimetabolite resistance", or not.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection

desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 8 recites the broad recitation of a change in fermentation procedure, and the claim also recites a change in culture medium which is the narrower statement of the range/limitation.

In claim 14 there is no clear and positive prior antecedent basis for the phrase "... sequences which code for ketopantoate reductase. . ." in claim 1, upon which claim 14 is dependent. It would be remedial to amend the claim 14 or claim 1 to provide antecedent basis for the cited phrase.

Claim 15 is vague and indefinite that the metes and bounds of the phrase "... wherein compatible plasmid vectors which contain the genes are employed. . ." are unclear. It is unclear as the claim is written how the vectors are to be employed (e.g. what methods steps may be required to "employ" the vector). It would be remedial to amend the claim language to more clearly indicate exactly how the vectors are to be employed.

Claim 17 is vague and indefinite in that the metes and bounds of the phrase "... one or more plasmid vector(s) compatible with one another is employed . . ." are unclear.

It is unclear exactly how the vectors are to be "employed". Also, there is no clear and positive antecedent basis for the term "the genes mentioned". Moreover, the metes and bounds of the phrase "... the genes being arranged in succession and placed under the control of a common promoter or arranged separately from one another under the control of various promoters. . ." are unclear. It is unclear which combinations of genes and promoters are acceptable in order to satisfy the claim limitations. It would be remedial to amend the claim language to clearly indicate which combinations of genes and promoters can meet the intended claim limitations.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliot can be reached on (703) 308-4003. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gerald G Leffers Jr.
Examiner
Art Unit 1636

ggj

ggj
December 17, 2001

David G. Goto
DAVID GOTO
PRIMARY EXAMINER